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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,130	08/19/2005	Michael Ziegler	82292	1507

23685 7590 07/06/2007  
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SOUTHBOROUGH, MA 01772

EXAMINER
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WRIGHT, PATRICIA KATHRYN

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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07/06/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/502,130	ZIEGLER, MICHAEL	
	<b>Examiner</b>	<b>Art Unit</b>	
	P. Kathryn Wright	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-19, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-19, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/2005</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The preliminary amendment filed July 19, 2005 has been entered and considered. Claims 5, 20 and 23 are cancelled. Claims 1-4, 6-19, 21-22 are currently pending.

### ***Specification***

2. The specification is objected to because the following sections (Background of the Invention, Brief Summary of Invention, etc.) of the specification are missing.

3. Furthermore, the "Brief Description of the Several Views of the Drawing" portion should include a brief description of Figs 9 and 10. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4, 6-19, and 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Applicant is respectfully reminded that a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "few optical reflections", and the claim also recites "preferably no optical reflections" which is the narrower statement of the range/limitation.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the means to provide the chamber with no optical reflections. How is this accomplished?

Claim 4 recites the image-recording device is aligned with and focused on the container at an acute angle. It is not clear which axis (vertical, horizontal) the angle is determined.

Claim 7 recites "in each case on both sides of the container located in the analysis position is a lateral lamp...". What sides? Does applicant mean top side, bottom side, lateral sides, etc?

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 6, 13-14, 19 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Watson et al. (WO 99/28724), hereinafter Watson.

Watson teaching an arrangement for analyzing body fluids having an image-recording device 22 (color image digital camera) connected to an electronic image evaluation apparatus (controller, not shown) and a barcode scanner 20. The body fluid is provided in container 14 inside a chamber 10 believed to have few optical reflections provided by the bias in the variation in brightness of the illumination means 142. In the analysis position, the image recording device is aligned with and focused on the container, and an illuminating devices 142 for illuminating the container from above and below. The Watson arrangement also includes a pair of grippers 146 capable of holding the tube by a predetermined angle so that the camera can capture images of the sample through a portion or window of the tube not obscured by the label 88. The image-processing methodology of claims 21-22 is taught at page 21, line 3+ of Watson.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 4 and 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson (WO 99/28724) in view of Chandler (US Patent No. 6,139,800).

The teachings of Watson have summarized previously, *supra*. Watson does not teach a lateral lamp arranged on both sides of the container. The arrangement being such that the mid points of the two lamps and the mid point of the container lie on a straight line (A), and a middle lamp is provided and arranged in such a way that the mid points of this middle lamp and the container lie on a straight line (B). Line B runs perpendicular to the line (A).

Chandler teaches an apparatus for use in assays. The apparatus includes a lateral lamp 12, 16 arranged on both sides of a container 1 (see Fig. 4). The

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arrangement being such that the mid-points of the two lamps and the mid-point of the container lie on a straight line (A). See figure 4 of Chandler. Furthermore, a middle lamp 14 is provided and arranged in such a way that the mid points of this middle lamp and of the container, likewise, lie on a straight line (B), which runs perpendicular to the line (A).

With respect to claim 8, Chandler teaches the optical axis of the image recording device 10 runs in a vertical plane that is perpendicular to the line (A). The line (B) lies in this vertical plane, see Fig. 4. Please note that Chandler teaches that while laser diodes are preferred, other optical sources/detectors are suitable.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to have included in Watson, the specific optical and detector configuration taught in Chandler in order to provide a multitude of excitation wavelengths at no significant and/or measurable cost to measurement accuracy.

Regarding the specific spacing of each lamp from the container being sixty millimeters (claim 10) and the difference in height between the lateral lamps and middle lamp is sixteen millimeters. It would have been an obvious matter of design choice to make the spacing between each lamp from the container sixty millimeters and the difference in height between the lateral lamps and the middle lamp sixteen millimeters, in the combined system of Watson and Chandler, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

11. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watson (WO 99/28724) in view of Toshiaki (JP 09-133687).

The teachings of Watson have summarized previously, *supra*. Watson does not recite an anti-reflection plate arranged on the side of the container and turned away from the image recording device.

Toshiaki does teach an anti-reflection plate (plastic body or piece of paper) made of a white or gray material placed behind the tube when the image is recorded, in order for the background to be as uniform as possible and arranged on the side of the container, turned away from the image recording device, see paragraph [0042] of Detailed Description section of Toshiaki (see attached translation). The flexible paper is believed capable of creating a concave depression adapted to conform to the peripheral shape of the container. It is obvious to a person skilled in the art that is measure is most effective if the material is in direct contact with the label, not only along a line of contact but over entire rounded surface of the container. Furthermore, it would have been obvious to the skilled artisan that the material not have a visually disruptive, abrupt structure, even in places where it is not lying flat. Thus, one would have inevitably caused a skilled person in the art to round the edges, as set forth in claim 17.

With respect to claim 18, the anti-reflection material is arranged such that it "can be" moved away from the container by a person. Note that the method of using holds no patentable weight in an apparatus claim. Only structural language is determinative of the metes and bounds of a patent apparatus claim. Functional recitations, standing



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alone, while perhaps helpful in understanding the meaning of a claim and the invention that it represents, cannot be relied upon to distinguish over the prior art. Nevertheless, functional language in the claims must be given full weight and may not be disregarded in evaluating the patentability of the subject matter defined employing such functional language. However, an applicant must establish that what is expressly taught by the prior art does not inherently function in the manner required by the claim.

Furthermore, with respect claim 18, it has been held that the recitation that an element "can" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to have included in Watson, the specific optical and detector configuration taught in Toshiaki in order to provide an anti-reflection plate to make the exterior of the tube as uniform as possible to remove the background noise resulting from a tube with or without label.

### ***Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 21-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending Application No. 10/502,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a method for analyzing body fluids characterized in that an image recording device is used to produce at least one image of the body fluid location in a container that is analyzed by means of image processing software.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

14. No claims allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

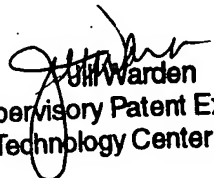
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 2, 2007

pkw

  
Jill Warden  
Supervisory Patent Examiner  
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